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Atty. Docket No.: P66317US0

REMARKS

The Office Action mailed December 18, 2002, has been carefully reviewed and by this Amendment, claims 5, 10-13, 15 and 16 have been canceled without prejudice or disclaimer, claims 1, 7 and 14 have been amended, and new claims 17-23 have been added. Accordingly, claims 1-4, 6-9, 14 and 17-23 are pending in the application. Claims 1, 7 and 19 are the independent claims. In view of the above amendments and the following remarks, favorable reconsideration of this application is respectfully requested.

As an initial matter, an Interview Summary was provided with the Office Action to which this Amendment responds. Information contained within this Interview Summary is incorrect for the following reasons.

On December 3, 2002, Applicants' representative, Suzin Bailey, was contacted by Examiner Bogart regarding the Examiner's determination that the present invention contained four inventions, namely Group I, directed to a catheter device (claims 1-6 and 14-16); Group II, directed to a first method of producing the catheter device (claims 7-9); Group III, directed to a second method of producing the catheter device (claims 10-11); and Group IV, directed to a third method of producing the catheter device

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(claims 12-13). Examiner Bogart required restriction and Ms. Bailey requested time to confer with Applicants.

On December 12, 2002, Ms. Bailey contacted Examiner Bogart to elect Group I, with the traverse that since the language of claims 7-9 is nearly identical with that of claim 1, 2 and 6, respectively, Groups I and II were not patentably distinct, making examination of claims 7-9 along with claims 1-6 and 14-16 proper. No traverse was made with respect to Groups III and IV.

However, in an Interview Summary which was provided with the Office Action the Examiner, referring only to a telephone contact made with Harvey Jacobson on December 9, 2002, stated that it was Applicants' position that "the method and apparatus were not patentably distinct". This is incomplete for the reasons already provided, namely that it is Applicants' position that the method of claims 7-9 is not being patentably distinct from the apparatus claims 1-6 and 14-16. The methods set forth in Groups III (claims 10-11) and IV (claims 12-13) are directed to processes of manufacture which are clearly not of comparable scope with Groups I and II so as to be properly examined as a single invention therewith.

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Accordingly, in that the subject matter of claims 10-13 is patentably distinct from that of claims 1-9 and 14-16, Applicants have herein canceled claims 10-13 and expressly reserve the right to file one or more divisional applications in order to pursue the independently patentable subject matter represented by this canceled subject matter.

By this Amendment, Applicants have amended the specification to correct informalities noted therein.

In response to the Examiner's rejection of claims 5 and 15 under 35 U.S.C. 112, second paragraph, as being indefinite, and rejection of claim 15 under 35 U.S.C. 101, Applicants have herein canceled claims 5 and 15.

The Examiner rejected claims 1, 2, 7, 8 and 10-15 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,656,675 to Fajnsztajn in view of U.S. Patent No. 6,165,159 to Blanton. (It appears that the Examiner's reference to "Leise Jr." appearing subsequently in the discussion of this rejection was inadvertent and therefore this reference is not discussed herein.) The Examiner also rejected claims 3, 4, 6 and 9 under 35 U.S.C. 103(a) as being unpatentable over Fajnsztajn and Blanton and further in view of U.S. Patent No. 5,685,870 to Tanghøj, and rejected claim 5 as being unpatentable over

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Fajnsztajn, Blanton and Tanghøj, and further in view of U.S.
Patent No. 5,211,640 to Wendler.

As set forth in amended claim 1, the present invention is directed to an external urinary catheter device having a contact member which is adapted to be engaged with at least the extreme portion of a penis, an opening formed in a distal end section of the contact member and positioned substantially opposite the urethral orifice in the position of use, and a discharge conduit connected with the opening to provide a sealed urine flow passage extending in a substantial axial direction towards the exterior of the catheter device. An aperture is provided in a distal part of the contact member or in the discharge conduit, and a membrane capable of selectively passing gases but retaining urine is fastened to the surface surrounding the aperture. The membrane is at least partly protected by a shield, a portion of the shield overlying the membrane including at least one vent for allowing gases to be in substantially unhindered contact with the external surface of the membrane.

Fajnsztajn discloses a urinary drainage device having an aperture 6 covered by a membrane capable of selectively passing gas. However, as correctly noted by the Examiner,

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Fajnsztajn does not disclose a shield, and further does not disclose a vent associated with the shield.

Blanton discloses the provision of a vent in an ostomy bag on the side of the bag facing the user. The vent opening is covered by a porous pad 60 of gauze or similar material that is arranged in a pouch 22. The pouch is sealed along three sides against the bag, and is open on the fourth side facing upward to allow periodic removal and replacement of the pad. The pad and surrounding pouch prevent gas and/or fecal matter from escaping from the bag and also from contacting the patient. Therefore, Blanton teaches against a vent in the pouch, i.e., the "shield", particularly in that portion of the pouch overlying the aperture, as such would undesirably allow exiting matter to come into contact with the ostomy patient.

For at least the foregoing reasons, claims 1 and 7 are patentable over the prior art; favorable consideration is requested. Claims 2-4, 6, 8, and 9 are also in condition for allowance as claims properly dependent on an allowable base claim and also for the subject matter contained therein.

Dependent on claim 1, new claim 17, as supported in the specification at page 26, lines 28-32, sets forth the embodiment of the vent as a plurality of apertures in the shield overlying

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the membrane, allowing a virtually unimpeded diffusion of gas between the membrane and the surrounding environment. Again, this is not disclosed or suggested by the prior art but, rather, Blanton teaches against such a construction. Specifically, the planar area of the pouch 22, which faces the user's skin (column 3, lines 27-30), cannot have holes therein as this would enable gas and/or fluid escaping through the porous pad 28 to contact the user's skin, clearly a most objectionable outcome.

New claim 18, supported in the specification at page 26, lines 25-28, specifies that the membrane is fastened to the surface surrounding the aperture with an element that provides a raised platform for the shield, thus forming an increased space between the shield and an external side of the membrane. This is not shown by Blanton and would not be suggested because a construction which created increased space between the pouch 22 and the inside surface of the bag would only serve to create an unwanted pressure point against the wearer.

New independent claim 19, in addition to most of the elements of claim 1, sets forth the embodiment of the present invention in which the vent includes at least one track, as shown in Figures 6-12 and discussed in the specification at pages 26-28. There is nothing in Fajnsztajn or Blanton which would

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suggest this construction for the same reasons already discussed in connection with new claim 17. In addition, as Fajnsztajn does not teach a shield, there would be no suggestion to add tracks to the membrane 6 as such membrane is already fully exposed for venting.

New claims 20 and 21 are also allowable over the prior art, setting forth embodiments in which the membrane is depressed in the surface of the discharge conduit and the vent includes one or more tracks in the edge of the shield or extending from the membrane to a point beyond the shield (see the specification at page 26, line 33 to page 27, line 28).

As set forth in new claims 22 and 23, the present invention may also be embodied with a tubular shield which is not shown in the prior art, the membrane being depressed in the discharge conduit and vented by a plurality of tracks in the edge of the shield or on the inner face thereof (see the specification at page 27, line 13 to page 28, line 12).

Favorable consideration and allowance of the new claims is requested.

Attached hereto is a marked-up version of the changes made to the application by the current amendment. The attached pages are captioned "Version with Markings to Show Changes Made".

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With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

On page 10, the second full paragraph has been amended as follows:

--Another suitable inner member which is arrangeable between the foreskin and the corona of a penis or solely on the corona of a penis, e.g., in the absence of foreskin in case of circumcising, comprises a plurality of leaves connected to a housing. The leaves are comprised of a film having an adhesive layer on their interior surface thereof to secure an attachment of the device to the corona of the penis. Preferably, the film as well as the adhesive layer is vapour permeable to increase the comfort of the wearer. An inner member of this kind is disclosed in [US] U.S. Patent No. 5,263,947 [and US 5,263,947], the entire disclosure thereof being incorporated herein by reference.--

IN THE CLAIMS:

Claims 5, 10-13, 15 and 16 have been canceled and claims 1, 7 and 14 have been amended as follows:

1. (Amended) An external urinary catheter device for the relief of male urinary incontinence, comprising:

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a contact member which is adapted to be engaged with at least the extreme portion of a penis[,];

an opening formed in a distal end section of the contact member and positioned substantially opposite the urethral orifice in the position of use[,];

a discharge conduit connected with the opening to provide a sealed urine flow passage extending in a substantial axial direction towards the exterior of the catheter device[,];

[wherein,]

an aperture [is] provided in a distal part of the contact member or in the discharge conduit[,];

a membrane [is] fastened to the surface surrounding said aperture, the membrane being capable of selectively passing gases but retaining urine[,];

a shield [is] at least partly protecting the membrane[,]; and

at least one vent [is] arranged in a surface of said shield overlying said membrane for allowing gases to be in substantially unhindered contact with the external surface of the membrane.

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7. (Amended) A process for production of an external urinary catheter device for the relief of male urinary incontinence, which comprises the steps of:

providing a catheter part [comprising] including a contact member which is adapted to be engaged with a penis[;], an opening formed in a distal end section of the contact member and positioned substantially opposite the urethral orifice in the position of use[;], and a discharge conduit connected with the opening to provide a sealed urine flow passage extending in a substantial axial direction towards the exterior of the catheter device[,];

providing an aperture in a distal part of the contact member or in the discharge conduit[,];

fastening a membrane to the surface surrounding said aperture, the membrane being capable of selectively passing gases but retaining urine[,];

providing a shield to protect the membrane[,]; and

arranging at least one vent in a surface of said shield overlying said membrane for allowing gases to be in substantially unhindered contact with the external surface of the membrane.

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14. (Twice Amended) [A kit for relief of male urinary incontinence comprising] The external urinary catheter device according to claim 1, in further combination with:

[an external urinary catheter device according to claim 1,]

a bag for collection of urine discharged from the catheter device[,]; and

a hose member connecting the catheter device and the bag.